R E M A R K S

Corrected English-Language Translation of PCT/JP03/01897

This application is a U.S. national phase application of PCT/JP03/01897.

A corrected English-language translation of the International application PCT/JP03/01897, along with a paper entitled SUBMISSION OF CORRECTED TRANSLATION, is being filed concomitantly herewith and is directed to the attention of the USPTO's PCT Legal Administration branch.

Amendment to the Title:

The title was amended to correspond to the title in said corrected translation.

Amendment to the Specification

An amendment was made to page 3 of the specification to correct a citation of a publication. The citation of the publication is correctly set forth on the Form PTO/SB/08B dated November 9, 2004.

Objection to the Disclosure

The disclosure in the specification was objected to for the reason set forth at the middle of page 2 of the April 1, 2008 Office Action.

This objection concerned the spelling of th word "periocularly." This objection is moot because in the aforesaid corrected English-language translation, the term "periocularly" has been replaced with the term "subconjunctivally."

Withdrawal of this objection is respectfully requested.

Claim Objections

Claims 1 and 8 were objected to for the reasons set forth at the bottom of page 2 of the Office Action.

This objection concerned the spelling of "periocularly." In view of the change in term "periocularly" to --subconjunctivally-- in the aforesaid corrected English-language translation, the claims were similarly amended hereinabove to recite --subconjunctivally-- instead of "periocularly."

Withdrawal of this objection is respectfully requested.

Claim Amendments

Claims 1 and 2 were amended to include the features of claim 5.

Claims 6, 8 and 16 were amended to recite diseases set forth on page 6, lines 10 to 16 of the originally filed specification.

Claims 3, 9 and 13 were amended to replace "an average particle diameter" with --a particle diameter--. This amendment is supported in the paragraph bridging pages 5 and 6 of the originally filed specification.

Minor editorial amendments were made to claims 7 and 12 with respect to inserting the term --drug-- after the term "anti-inflammatory."

Rejections Under 35 USC 112, First Paragraph

1. Claims 8 to 12 were rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement for the reasons stated on pages 3 to 4 of the Office Action.

The position was taken in the Office Action that the recitation in claim 8 of a "disease of a posterior segment" and

the recitation in claim 11 of "posterior segment is a retina, a choroid, an optic nerve, a vitreous body or a crystalline lens" is not sufficiently described in the specification for the "myriad of diseases for the number of tissues, organs and vessels embraced by the claims."

In the aforesaid corrected English-language translation, all occurrences of "posterior segment" were changed to --posterior segment of an eye-- or --posterior segment of the eye--. The claims were likewise amended hereinabove.

Claim 8 was amended hereinabove to recite the following specific diseases: uvetis, cytomegalovirus retinitis, age-related macular degeneration, diabetic retinopathy, proliferative vitreoretinopathy, retinal detachment, pigmentary retinal degeneration, central retinal vein occlusion and central retinal artery occlusion. These specific diseases are disclosed on page 6, lines 10 to 16 of the specification.

Claim 11 was canceled hereinabove.

2. Claims 6, 8 to 12 and 16 were rejected under 35 USC 112, first paragraph, for allegedly failing to comply with the

enablement requirement for the reasons indicated beginning at the middle of page 4 and continuing to the middle of page 6 of the Office Action.

The position was taken in the Office Action that "the specification does not provide for any method of treatment for any condition or prevention of any condition" (see page 6, lines 4 to 5 of the Office Action).

Claims 6, 8 and 16 were amended to recite the aforesaid following specific diseases: uvetis, cytomegalovirus retinitis, age-related macular degeneration, diabetic retinopathy, proliferative vitreoretinopathy, retinal detachment, pigmentary retinal degeneration, central retinal vein occlusion and central retinal artery occlusion. Moreover, claim 11 was canceled hereinabove.

Based on the data of drug delivery of betamethasone to the retina-choroid after conjunctival administration (see Example 3 of the present specification), and the data of neovascularization inhibition effect (see Example 4 of the present specification), it is respectfully submitted that a person having ordinary skill in the art would readily be able to implement the presently

claimed invention for treating or preventing the diseases recited in applicants' present claims. It is therefore respectfully submitted that the specification meets the enablement requirement in view of applicants' present claims.

Withdrawal of each of the 35 USC 112, first paragraph rejections is respectfully requested.

Rejection Under 35 USC 112, Second Paragraph

Claims 1 to 17 were rejected under 35 USC 112, second paragraph, for the reasons beginning at the bottom of page 6 and continuing to the middle of page 7 of the Office Action.

As discussed above, the present claims recite "posterior segment of an eye" or "posterior segment of the eye." Moreover, applicants' present claims 1 and 2 recite that the "posterior segment of an eye" is "a retina, choroid, an optic nerve, a vitreous body or a crystalline lens," based on the features recited in original claims 5 and 15.

Withdrawal of the 35 USC 112, second paragraph rejection is therefore respectfully requested.

Rejection Under 35 USC 102

Claims 1 to 17 were rejected under 35 USC 102 as being anticipated by JP 2000-247871 to Ogura et al. for the reasons set forth beginning at the bottom of page 7 and continuing to the bottom of page 8 of the Office Action.

The position was taken in the Office Action that Ogura et al. (JP 2000-247871) disclose a method of treating a disease of a posterior segment of an eye comprising administering a periocular injection which comprises fine particles containing a drug and enabling the drug to be delivered to the posterior segment.

According to Ogura et al., there is a description of administering fine particles "into the vitreous body." However, there is no description of administering fine particles "subconjunctivally" at all in Ogura et al. On the other hand, applicants' present claims relate to a drug delivery system comprising fine particles that are "subconjunctivally" administered and a method of treating and/or preventing a disease of a posterior segment of an eye comprising subconjunctivally administering said fine particles. Therefore, it is respectfully submitted that applicants' present claims are clearly

substantially different from Ogura et al. with respect to the administration site of the fine particles.

Withdrawal of the anticipation rejection is therefore respectfully requested.

Moreover, Ogura et al. use as a carrier nanospheres where the average diameter of the fine particles is on the order of nanometers, whereas applicants' present claims recite as a carrier microspheres where the diameter of the fine particles is on the order of micrometers. That is, there is no teaching or suggestion in Ogura et al. of a subconjunctival administration of fine particles containing a drug and the use of microspheres as a carrier. The fact that the combination of such a carrier (microspheres) and such an administration site (subconjunctival administration) can bring about a favorable drug delivery to the posterior segment of an eye had not been found until the present inventors first discovered this as a result of their intense study. Therefore, it is respectfully submitted that applicants' present claims are not obvious in view or Ogura et al.

Double Patenting Rejection

Claims 8 to 12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 to 12 and 14 of copending application Serial No. 10/568,892 for the reasons indicated on pages 8 to 9 of the Office Action.

Applicants' present claim 8 relates to a method for treatment and/or prevention of a disease of a posterior segment of an eye comprising subconjunctivally administering to a patient fine particles containing a drug, whereas copending application Serial No. 10/568,892 relates to a method for the treatment or prevention of a disease of a tissue in the posterior segment of an eye comprising carrying out a sub-Tenon administration of fine particles. Applicants' present claims thus substantially differ from claims 10 to 12 and 14 of copending application Serial No. 10/568,892 with respect to the administration site of fine particles.

Moreover, drug delivery to the anterior segment of an eye is prevented in copending application Serial No. 10/568,892 (sub-Tenon administration of fine particles), while such an action is not afforded by applicants' present claim 8 (subconjunctival

administration of fine particles). See Table 4 on page 22 of copending application Serial No. 10/568,892. It is respectfully submitted that a person having ordinary skill in the art would not expect such a clear difference in action between applicants' present claims and the claims of copending application Serial No. 10/568,892.

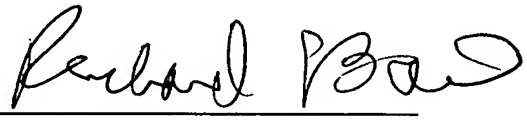
It is noted that prevention of a drug from being delivered to the anterior segment of an eye is a clinically very useful action, since this action helps to decrease side effects such as increased intraocular pressure caused by steroid administration.

Withdrawal of the double patenting rejection is therefore respectfully requested.

Reconsideration is requested. Allowance is solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,



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